

Message

From: Perovich, Gina [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6E3C19D7F4DB41BFA2477AA27AD83945-PEROVICH, GINA]
Sent: 4/7/2016 2:12:53 PM
To: ORD-NCEA-IRIS [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1d418fba8be24d3ba56b0ca264b7360e-ORD-NCEA-IRIS]
Subject: FW: Transmittal notification: 16-I-OPAR-000086 - DCR- Order 1000.17A - Policy and Procedures on Protection of Human Research Subjects in EPA Conducted or Supported Research
Attachments: SA signed memo.pdf; 2016 Policy Order Revision 3_1_16.docx

Gina Perovich
Deputy Director
IRIS Program
USEPA/ORD/NCEA
703-347-8656

From: Saint, Chris
Sent: Thursday, April 07, 2016 9:54 AM
To: Hagerthey, Scot <Hagerthey.Scot@epa.gov>; Perovich, Gina <Perovich.Gina@epa.gov>; Walsh, Debra <Walsh.Debra@epa.gov>; Johnson, Craig <Johnson.Craig@epa.gov>; Ross, Mary <Ross.Mary@epa.gov>
Subject: FW: Transmittal notification: 16-I-OPAR-000086 - DCR- Order 1000.17A - Policy and Procedures on Protection of Human Research Subjects in EPA Conducted or Supported Research

FYI – You may want to pass this on to those who use data from human studies.

Chris

Chris Saint
Director, PSS/NCEA
(703) 347 0317

From: ORD-Transmittals@epa.gov [mailto:ORD-Transmittals@epa.gov]
Sent: Thursday, April 07, 2016 8:02 AM
To: ORD-Mgmt-Council <ORDMgmtCouncil@epa.gov>
Cc: Wade, Andre <Wade.Andre@epa.gov>; ORDExecCouncil@epa.gov; ORD-POS-Directors <ORDPOSDirectors@epa.gov>
Subject: Transmittal notification: 16-I-OPAR-000086 - DCR- Order 1000.17A - Policy and Procedures on Protection of Human Research Subjects in EPA Conducted or Supported Research

ORD INFORMATION TRANSMITTAL

Transmittal Subject:	DCR- Order 1000.17A - Policy and Procedures on Protection of Human Research Subjects in EPA Conducted or Supported Research
Response Due Date:	

Contact Organization: OPARM

Background Information

ORD's Office of the Science Advisor request a revision to Order 1000.17A, *Policy and Procedures on Protection of Human Research Subjects in EPA Conducted or Supported Research*. These revisions have been reviewed by The Human Research Ethics Council (HREC), a cross-agency council formed to promote consensus on Agency policies and procedures for research involving human participants. The HREC concurred with the proposed revisions.

The current Order was approved May 27, 2011 and amended on July 27, 2011.

Analysis

Order 1000.17A is the EPA's policy for the protection of human subjects in Agency's conducted or supported research. It has not been substantively updated since 1999. The 2011 amendment to the Order consisted of adding language that reinforced that all human observational exposure studies would be conducted in accordance with the principles outlined in the agency Scientific and Ethical Approaches for Observational Exposure Studies (SEAOES) document. Since 2011, research and agency practices have evolved, and the proposed revisions ensure that the Agency's policy reflects both accurate regulatory language and contemporary research practice. The attached memorandum from Thomas Burke outlines the proposed revisions.

Action/Instruction for Response

Responses to this Directive Clearance Review are welcomed but not necessary.

Responses should be submitted via email to OPARM's Andre Wade at wade.andre@epa.gov. Please indicate whether any comments are "advisory" or "issue resolution requested". Also, if applicable, indicate if your organization has "no comments". This information is due to OPARM by COB Tuesday, April 19, 2016

If you have any questions concerning this DCR, Andre Wade can be reached at (202) 564-3697.

Point of Contact:	Andre Wade [Wade.Andre@epa.gov]
Phone:	202-564-3697
ID:	16-I-OPAR-000086
Fiscal Year:	2016

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